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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GODDARD, LAURA B

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/961,086	Applicant(s) ROSS ET AL.	
	Examiner LAURA B. GODDARD	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/17/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 17, 2008 has been entered.

Claims 5 and 39 submitted 1/25/2008, were renumbered claims 1 and 2, respectively, at allowance. Claims 1 and 2 are currently pending and being examined.

Priority

2. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Provisional Application No. 60/073,763, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for both claims of this application.

The instant claims are drawn to an isolated monoclonal antibody which binds to SEQ ID NO:1 (claim 1), and a method of screening a sample for a polypeptide consisting of SEQ ID NO:1, said method comprising contacting a test sample with the antibody of claim 1, and detecting binding of said antibody to said polypeptide, thereby screening a sample for a polypeptide consisting of the amino acid sequence of SEQ ID NO:1 (claim 2).

The instant specification discloses that SEQ ID NO:1 is a 655 amino acid BCRP polypeptide that is approximately 72.3 kDa (p. 5). The amino acid sequence is disclosed in Figure 2A as a 655 amino acid polypeptide, as well as in the sequence listing.

Provisional Application No. 60/073,763 discloses that BCRP polypeptide is a 663 amino acid polypeptide (eight amino acids longer) that is approximately 73.2 kDa (see p. 3 "Summary of the Invention" for 60/073763). Application 60/073763 discloses a 663 amino acid polypeptide in Figure 2A as SEQ ID NO:1 (see "Figure 2A" for 60/073763), and claims a BCRP protein that is about 663 amino acids in length (claim 1), that has a molecular weight of about 73 kDa (claim 2), which is substantially identical to SEQ ID NO:1 (claim 3) and an antibody which binds to the protein of claim 1 (claim 4) (see "Claims" for 60/073763) .

Further, the inventors published the 663 amino acid sequence of 60/073763 in Doyle et al, PNAS, December 1998, 95:15665-15670, IDS, in Figure 2A and teach that it is 663 amino acids long in the abstract.

Given Provisional Application No. 60/073,763 discloses a different 663 residue polypeptide as SEQ ID NO:1 and antibodies that bind it, the disclosure of the prior-filed

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application, Provisional Application No. 60/073,763, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for both claims 1 and 2 of the instant application drawn to monoclonal antibodies which bind a 655 residue polypeptide SEQ ID NO:1. **Therefore, the earliest priority date for the instant application is 2/5/1999**, which is the filing date of Non-provisional Application 09/245,808 that discloses SEQ ID NO:1 as the same 655 amino acid polypeptide disclosed in the instant application.

See IDS submitted 6/17/2008, item CC, European Opposition to European Patent No. 1054894, for similar reasoning given above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allikmets et al (Cancer Research, December 1, 1998, 58:53337-53339, IDS) in view of Campbell, A. (Laboratory Techniques in Biochemistry And Molecular Biology, Volume 13, Chapter 1, pages 1-33, 1984) (see sequence search Result #1, Uniprot database, "20080917_142909_us-09-961-086a-1.rup").

The claim is drawn to an isolated monoclonal antibody which binds to SEQ ID NO:1 (claim 1), and a method of screening a sample for a polypeptide consisting of SEQ ID NO:1, said method comprising contacting a test sample with the antibody of claim 1, and detecting binding of said antibody to said polypeptide, thereby screening a sample for a polypeptide consisting of the amino acid sequence of SEQ ID NO:1 (claim 2).

Allikmets et al teach a 655 amino acid polypeptide identical to SEQ ID NO:1 of the instant application, with the exception of a T to R mutation at position 482 (see sequence search Result #1, Uniprot database, “20080917_142909_us-09-961-086a-1.rup”). Allikmets et al teach this polypeptide belongs to a family of proteins including transporter proteins and multi-drug resistance genes and is highly expressed in the placenta (abstract; Figure 2). Allikmets et al suggests further study of the function and regulation of the polypeptide (p. 53339, col. 1) and that it may play an important role in transport of specific molecules into or out of the placenta (abstract).

Allikmets et al does not teach monoclonal antibodies that bind to the polypeptide or methods of screening a sample for a polypeptide consisting of SEQ ID NO:1 using said antibodies.

Campbell summarize production of (Figure 1.1) and uses for monoclonal antibodies and teach that it is “customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)” (page 29). Campbell teach monoclonal antibodies can be used in diagnostics and protein detection using common

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techniques such as immunocytochemistry and radioimmunoassay, which are assays that inherently include steps of contacting monoclonal antibodies to samples to detect binding of the antibodies to polypeptides (p. 18-19).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made and one would have been motivated to make monoclonal antibodies that bind to SEQ ID NO:1 because it is conventional in the art to generate antibodies following the cloning of a gene for further studies. Campbell teaches (page 29) that it is “customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)”. Further, the Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonal antibodies against it is *prima facie* obvious. See *Ex parte Ehrlich*, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), *Ex parte Sugimoto*, 14 USPQ 2d 1312 (PTO Bd. Pat. App. & Int. 1990). Thus given the isolated antigen of Allikmets et al, it would have been *prima facie* obvious to make monoclonal antibodies to the prior art polypeptide, and given the 99.8% identity to SEQ ID NO:1, a large subset of monoclonal antibodies that bind the polypeptide taught by Allikmets et al would also bind SEQ ID NO:1. One would have been motivated to produce antibodies to the polypeptide taught by Allikmets et al because it is conventional practice to produce an antibody that recognizes that protein which serves as a tool in determining the protein's functions.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made and one would have been motivated to screen samples for

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detection of the polypeptide taught by Allikmets et al using monoclonal antibodies in order to study the polypeptide expression and function in placenta, as suggested by Allikmets et al, and because Campbell teach that immunochemical techniques of protein detection using monoclonal antibodies are known. Given the monoclonal antibodies taught by the combined references would also bind SEQ ID NO:1, screening methods using said monoclonal antibodies would also detect a polypeptide consisting of SEQ ID NO:1. One of ordinary skill in the art would have a reasonable expectation of success screening a sample for the polypeptide by detecting monoclonal antibody binding to the polypeptide in the sample because immunochemical techniques are known and successful.

4. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession No. AAC97367 (GI:4038352), publicly available on NCBI 12/21/1998 (item "W" in IDS submitted 6/17/2008) in view of Campbell, A. (Laboratory Techniques in Biochemistry And Molecular Biology, Volume 13, Chapter 1, pages 1-33, 1984), and as evidenced by "Sequence alignment of SEQ ID NO:1 and AAC97367" (IDS item "BB" submitted 6/17/2008).

The claim is drawn to an isolated monoclonal antibody which binds to SEQ ID NO:1 (claim 1), and a method of screening a sample for a polypeptide consisting of SEQ ID NO:1, said method comprising contacting a test sample with the antibody of claim 1, and detecting binding of said antibody to said polypeptide, thereby screening a

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sample for a polypeptide consisting of the amino acid sequence of SEQ ID NO:1 (claim 2).

GenBank Accession No. AAC97367 is a 655 amino acid breast cancer resistance protein that is 100% identical to SEQ ID NO:1 of the instant application (as evidenced by "Sequence alignment of SEQ ID NO:1 and AAC97367," IDS item "BB" submitted 6/17/2008).

GenBank Accession No. AAC97367 does not teach monoclonal antibodies that bind to the protein or a method of screening a sample for the protein using the monoclonal antibodies.

Campbell summarize production of (Figure 1.1) and uses for monoclonal antibodies and teach that that it is "customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29). Campbell teach monoclonal antibodies can be used in diagnostics and protein detection using common techniques such as immunocytochemistry and radioimmunoassay, which are assays that inherently include steps of contacting monoclonal antibodies to samples to detect binding of the antibodies to polypeptides (p. 18-19).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made and one would have been motivated to make monoclonal antibodies that bind to AAC97367 because it is conventional in the art to generate antibodies following the cloning of a gene for further studies. Campbell teaches (page 29) that it is "customary now for any group working on a macromolecule to both clone

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the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)". Further, the Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonal antibodies against it is *prima facie* obvious. See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. App. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. App. & Int. 1990). Thus given the antigen of AAC97367 was known, it would have been *prima facie* obvious to make monoclonal antibodies to the AAC97367 protein. One would have been motivated to produce antibodies to AAC97367 because it is conventional practice to produce an antibody that recognizes that protein which serves as a tool in studying the protein and determining the protein's functions.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made and one would have been motivated to screen samples for detection of AAC97367 using monoclonal antibodies because Campbell teach using monoclonal antibodies to study proteins and that immunochemical techniques of protein detection using monoclonal antibodies are known. One of ordinary skill in the art would have a reasonable expectation of success screening a sample for the AAC97367 protein by detecting monoclonal antibody binding to the protein in the sample because immunochemical techniques are known and successful.

5. **Conclusion:** No claim is allowed.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard/
Examiner, Art Unit 1642